

The examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims. There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed. Furthermore, The absence of definitions or details for well-established terms or procedures should not be the basis of a rejection under 35 U.S.C. 112, para. 1, for lack of adequate written description.

Applicants submit that possession has been shown by describing an actual reduction to practice of the claimed invention. An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. It is well established, however, that the description need only describe in detail that which is new or not conventional.

The specification has provided ample data on the interaction between Smad6 and Hoxc-8, demonstrating clearly that Applicants had possession of the claimed invention at the time the

application was filed. The interaction between Smad6 and Hoxc-8 was identified in a yeast two-hybrid approach (Figure 1), and further demonstrated by co-immunoprecipitation assays in cells. Gel shift assays show that Hoxc-8 interacts with Smad6 as a heterodimer when binding to DNA. More importantly, the Smad6/Hoxc-8 complex inhibited both Smad1 interaction with Hoxc-8 in gel shift assays and transcription activity mediated by Smad1 (Figures 3 and 4B).

The Examiner contends that the specification does not provide any sequences for Smad6 or Hoxc-8 such that the skilled artisan would recognize the structural features of proteins encompassed in the terms Smad6 and Hoxc-8. Applicants respectfully disagree that sequence information for Smad6 or Hoxc-8 is necessary to meet the written description requirement of 35 U.S.C. §112, first paragraph.

Applicants submit that the practice of the present invention does not require knowledge of the structural features of Smad6 and Hoxc-8. The present invention only requires cloning Smad6 and Hoxc-8 into suitable vectors. Smad6 and Hoxc-8 are well known in the art and one of ordinary skill in the art can readily obtain published sequences for these proteins in the prior art and

clone these proteins according to standard genetic engineering procedures.

Applicants submit that the specification has provided sufficient written description for the claimed invention and possession of the invention has been shown by an actual reduction to practice of the claimed invention. Accordingly, Applicants respectfully request that the rejection of claims 11-14 under 35 U.S.C. §112, first paragraph, be withdrawn.

Claims 11-14 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The rejection is respectfully traversed.

The Examiner contends that it is unclear what proteins would be encompassed in the terms "Smad6" and "Hoxc-8". The Examiner further contends that it is unclear because the same proteins may be referred to in the prior art by an alternative name. Applicants respectfully disagree.

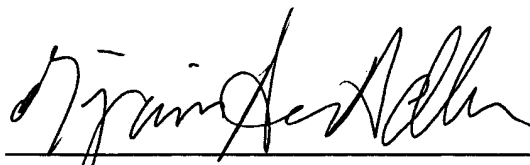
Applicants submit that Smad6 and Hoxc-8 proteins are well known in the art and have been extensively studied. One of ordinary skill in the art would readily recognize what these proteins are based on description and sequences readily available and

published in the prior art. Applicants further submit that one of ordinary skill in the art would not be confused by the purported situation of naming the same proteins with different names because Smad6 and Hoxc-8 proteins have been well characterized and well defined. Hence, Applicants submit that the Smad6 and Hoxc-8 proteins have been adequately described in the present application. Accordingly, Applicants respectfully request that the rejection of claims 11-14 under 35 U.S.C. §112, second paragraph, be withdrawn.

This is intended to be a complete response to the Office Action mailed January 14, 2003. If any issues remain outstanding, the Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution.

Respectfully submitted,

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